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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/814,123 03/22/01 HOGENKAMP

D 1861.1270001

026111 HM12/0913
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WASHINGTON DC 20005-3934

EXAMINER

SHAMEEM, G

ART UNIT	PAPER NUMBER
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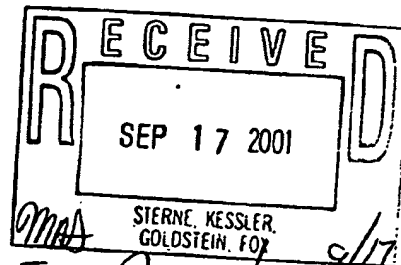
1626

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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JMC *9/17*
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DOCKETED

Response due Dec. 13, 2001

STAT BAR MARCH 13, 2002

Office Action Summary

Application No.

09/814,123

Applicant(s)

HOGENKAMP ET AL.

Examiner

Golam M. M. Shameem

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Status of Claims

Claims 1-23 are pending in this application.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 to 23, are rejected under 35 USC § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expressions "optionally substituted", "Het", "preferably", "can be" and "disorder responsive to", place no definite limits or boundaries on the claims. The rejection with respect to "optionally substituted" and "Het" could be overcome by changing them to substituted or unsubstituted with and heterocyclic ring respectively.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 to 21, are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is most nearly connected, to make and/or use the invention without undue experimentation. For rejection under 35 U.S.C. § 112, first paragraph, following factors must be considered in determining whether a disclosure meets the enablement requirement (In re Wands, 8 USPQ2d 1400, 1404 (CAFC,1988):

1. Nature of invention.
2. State of prior art.
3. Level of ordinary skill in the art.
4. Level of predictability in the art.
5. A mount of direction and guidance provided by the inventor.
6. Existence of working examples.
7. Breadth of the claims,
8. Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 19-21, are directed to "preventing or ameliorating" of neurodegenerative conditions, manic depression, neuropathic pain etc. to a mammal in need thereof. The claims refer to "preventing" of neuronal damage while all of the support in the specification enables "treating" and not "preventing". Because of the high level of unpredictability associated with the "preventing" of neuronal damage a greater amount of evidentiary support is needed in order to

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fully satisfy the requirement of 35 U.S.C. § 112, first paragraph. The applicant needs to provide sufficient guidance regarding "how to use" the invention properly. It has not been shown in the specification that the "preventing" of such disorders is accepted in the art as being predictive of the utility alleged, especially when absent of pharmacological data (testing protocol). Merely stating that the instant compounds are useful for "preventing" against of neuronal damage does not establish the usefulness of an invention absent art-recognized correlation between such tests and the ultimate use. Identifying substances as objects for further use testing (speculative utility) is insufficient to provide an enabling disclosure. See *Brenner v. Manson*, 148 USPQ689 or *In re Kirk*, 153 USPQ 48. Applicant does not give sufficient direction and guidance in enabling these claims. The quantity of experimentation required to make and use the invention based on the content of the disclosure would therefore be undue because of the level of unpredictability associated with "preventing" of neuronal damage. Therefore, the instant invention is not enabled. *Boar et al*, *Kadaba et al*, and *Matsuo et al* are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (703) 305-0116. The examiner can normally be reached on Monday-Friday from 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mckane, can be reached at (703) 308-4532. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other


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communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

Golam M M Shameem, Ph.D.
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Floyd D. Higel
Primary Patent Examiner
Art Unit 1626 *SR 1600*
Technology Center 1

September 6, 2001